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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,621	04/17/2000	Yuqiu Jiang	210121.470C5	1408

500 7590 06/26/2003

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EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 06/26/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/551,621

Applicant(s)

JIANG ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6 and 81-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 86, 88 and 89 is/are allowed.
- 6) ☐ Claim(s) 81-85 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Claims 81-85, and 87 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the Office Action mailed 12-16-2002.

Applicant's arguments filed 4-13-2003 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the disclosure adequately establishes possession of the full scope of the currently claimed invention. Moreover, Applicants argue that the skilled artisan would recognize that the tumor specificity of expression of B726P represents a distinguishing identifying characteristic common among the polynucleotides of the claimed invention.

Contrary to Applicant's assertions, it is first noted that the oligonucleotide recited in claim 83, that hybridizes to the sequence recited in SEQ ID NO: 474 under moderately stringent conditions, is not limited to those sequence that are useful in detecting breast cancer. Secondly, in regards to those claims that recite wherein the oligonucleotide or isolated polynucleotide hybridizes under moderately stringent conditions, it is noted that the definition for said moderately stringent conditions are not set forth such that the skilled artisan would immediately recognize with reasonable clarity, deliberateness, and precision, which hybridization conditions

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would produce the claimed nucleic acid molecules. According to the specification as filed, "[F]or purposes of illustration, suitable moderately stringent conditions for testing the hybridization of a polynucleotide of this invention with other polynucleotides include prewashing in a solution of 5XSSC, 0.5% SDS, 1.0 mM EDTA (pH 8.0); hybridizing at 50°C-65°C, 5X SSC, overnight; followed by washing twice at 65°C for 20 minutes with each of 2X, 0.5X and 0.2X SSC containing 0.1% SDS." See page 33, lines 3-11. It is noted that the conditions described by Applicants are described, "[F]or purposes of illustration," therefore it is apparent that other conditions may be included within the scope of Applicant's definition of the recited "moderately stringent conditions." Applicants do not specifically describe the hybridization conditions in such clear and concise terms that the skilled artisan would unequivocally know which hybridization conditions would be useful to produce the oligonucleotides of the present invention, wherein said oligonucleotides are capable of hybridizing to SEQ ID NO: 474 under said conditions and wherein said oligonucleotide would be useful for the detection of breast cancer.

Particularly, in regards to claim 85 that recites "[A]n isolated polynucleotide useful in the detection of breast cancer comprising a sequence complementary to the sequence provided in SEQ ID NO: 474," the scope of the instant claim encompasses polynucleotides of undefined length, comprising "a sequence" of undefined length, the is complementary to the sequence provided in SEQ ID NO: 474. The scope of this claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between the genus members are permitted, and neither the specification nor the claims provide any guidance as to what specific changes should be made such that the polynucleotide maintains its ability to

be useful in the detection of breast cancer. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. Since the disclosure fails to describe the common attributes or characteristics, specifically by way of sequence structure, that identify the members of the broad genus of polynucleotides encompassed by the instant claims, and because the genus is highly variant, the disclosed sequence of SEQ ID NO: 474, alone is not sufficient to represent claimed genus. For example, the instant claims consistently recite "a sequence of SEQ ID NO: 474," this phrase reads on "a sequence of SEQ ID NO: 474" corresponding to from one nucleotide to the entire length of SEQ ID NO: 474. Therefore, a sequence according to the present invention encompass those sequences having from only one common nucleotide up to the full length sequence of SEQ ID NO: 474, and still be encompassed by claim 85. Furthermore, in order to determine whether or not the sequences function for the detection of breast cancer, further experimentation must be performed for each individual sequence.

See the January 5, 2001 (Vol. 66, No. 4, pages 1099-1111) Federal Register for the Guidelines for Examination of Patent Applications Under the 35 USC 112 ¶ 1, "Written Description" Requirement. These guidelines state: "[T]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the

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invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that applicant was in possession of the claimed invention."

Since, as described above, further experimentation is necessary in order to determine if the full scope of sequences encompassed by the instant claims can actually be used for the detection of breast cancer, the full scope of the claimed invention was not ready for patenting at the time of filing of the instant application.

Conclusion

3. Claims 6, 86, and 88-89 are free if the prior art.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

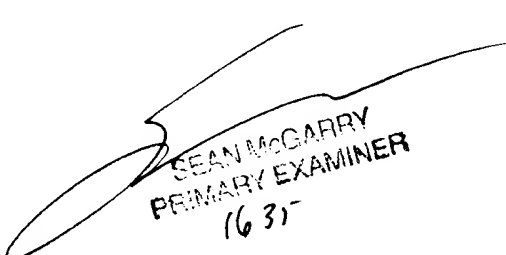
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Fri, 8:30AM-6: 30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635

JLE
June 19, 2003


SEAN MCGARRY
PRIMARY EXAMINER
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